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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,334	04/09/2001	Elmar Peschke	1348	8721

7590 11/18/2003

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	13

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,334	PESCHKE ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 July 2003 has been entered.

This Office Action is in response to Applicants' request for continued examination filed 24 October 2003. Claims 11-13 are under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although Applicants argue that the experimental results described on pages 3 to 6 demonstrate the effectiveness of administering melatonin as the effective ingredient, it should be noted that these experiments are wholly in vitro studies. As described below in the enablement rejection, there is inadequate guidance, art support, and working examples to establish any predictability regarding the use in vitro as

compared to in vivo. The limiting of the claims to use of melatonin does not give way to the required enablement as is suggested by Applicants.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of

experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method of treating hyperinsulinaemia comprising administering melatonin in an amount effective to inhibit insulin release in a living being suffering from hyperinsulinaemia.

The state of the prior art and the predictability or lack thereof in the art: The art teaches a level of unpredictability regarding melatonin activity for the purpose of regulating or inhibiting insulin release via beat cell islets, i.e., Bailey et al. 1974 (cited in previous office action). The instant specification only discloses in vitro melatonin applications and preparations for treatment of rat pancreatic cells. Although Bailey *et al.* teach significant reductions in basal insulin secretion from pieces of rat pancreas they teach that administration of melatonin in vivo does not significantly alter plasma insulin levels. As an example of the lack of predictability for in vivo use as claimed, Bailey *et al.* states, "A constant infusion of melatonin into rats undergoing intravenous glucose tolerance tests did not alter blood sugar levels and produced only a marginal decrease in plasma insulin levels." Thus, the predictability in the art is lacking as the art teaches that in vitro inhibition or reduction of insulin secretion by melatonin does not correlate with therapeutic efficacy in vivo.

The amount of direction or guidance present and the presence or absence of working examples: There are inadequate amounts of working examples in the specification, wherein it would not be obvious that the claimed invention would translate from in vitro experiments, disclosed on pages 3 to 6 of the specification, to in vivo administration of melatonin for

treatment of hyperinsulinaemia. Applicants have only used solutions with varying concentrations of melatonin. This does not capitulate into in vivo administration.

The breadth of the claims and the quantity of experimentation needed: Since the specification lacks predictability and due to the lack of working examples in the specification, it would require undue experimentation for one skilled in the art to make and/or use the invention commensurate with the breadth of the claimed inventions regarding in vivo treatment with melatonin.

Claim Rejections - 35 USC § 102

3. If Applicants overcome the present rejection under 35 U.S.C. 112, first paragraph, then the following rejection under 35 U.S.C. 102(e) would apply.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewy *et al.* (US Patent 6069164, 30 May 2000).

Under the principles of inherency, if a prior art method, in its normal operation, would necessarily perform the method claimed, then the method claimed will be considered as anticipated by the prior art method. (MPEP §2112.02).

The following rejection is based on the judicial precedent following *In re* Fitzgerald, 205 USPQ 594, because the prior art is silent with regard to efficacious in vivo treatment of hyperinsulinaemia by administering melatonin.

Lewy *et al.* teaches the administration of melatonin to a human for treating insomnia (columns 29-30). Under the principle of inherency and overlapping patient populations, there is a significant overlap in the patient population who are administered melatonin for treating sleep disorders and those suffering from hyperinsulinaemia. Thus, the claimed invention is anticipated via inherent properties and actions upon administration of melatonin.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
17 November 2003

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600